Docket Number: 50623.326

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	DesNoyer et al.	Examiner:	James William Rogers
Serial No.:	10/750,139	Art Unit:	1618
Filed:	June 3, 2004		

Title: Poly(Ester Amide) Coating Composition For Implantable Devices

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 CFR § 1.131

We, Jessica R. DesNoyer, Syed F.A. Hossainy, Stephen D. Pacetti, and Yiwen Tang declare as follows:

1. The application identified above was granted the filing date of June 3, 2004.

2. We conceived of or invented the subject matter of the application identified above in the United States prior to November 10, 2003. See Appendix A – redacted invention disclosure form.

3. We further declare that all statements made herein of our own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed at Santa Clara, California on this 2nd day of October, 2006.

By: Jessica R. DesNoyer
Jessica R. DesNoyer

Executed at Fremont, California on this _____ day of _____, 2006.

By: _____
Syed F.A. Hossainy

Executed at San Jose, California on this _____ day of _____, 2006.

By: _____
Stephen D. Pacetti

Executed at San Jose, California on this _____ day of _____, 2006.

By: _____
Yiwen Tang

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed at Santa Clara, California on this _____ day of _____, 2006.

By:_____
Jessica R. DesNoyer

Executed at Fremont, California on this _____ day of _____, 2006.

By:_____
Syed F.A. Hossainy

Executed at San Jose, California on this _____ day of _____, 2006.

By:_____
Stephen D. Pacetti

Executed at San Jose, California on this _____ day of _____, 2006.

By:_____
Yiwen Tang

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed at Santa Clara, California on this _____ day of _____, 2006.

By:_____
Jessica R. DesNoyer

Executed at Fremont, California on this _____ day of _____, 2006.

By:_____
Syed F.A. Hossainy

Executed at San Jose, California on this 26th day of Sept., 2006.

By: Stephen Pacetti
Stephen D. Pacetti

Executed at San Jose, California on this _____ day of _____, 2006.

By:_____
Yiwen Tang

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed at Santa Clara, California on this _____ day of _____, 2006.

By:_____
Jessica R. DesNoyer

Executed at Fremont, California on this _____ day of _____, 2006.

By:_____
Syed F.A. Hossainy

Executed at San Jose, California on this _____ day of _____, 2006.

By:_____
Stephen D. Pacetti

Executed at San Jose, California on this 4th day of Oct, 2006.

By:_____
Yiwen Tang

APPENDIX A

GUIDANT CONFIDENTIAL & PRIVILEGED

For Legal Department Use Only
Docket No.: 4135
Date Assigned: 5/14/03
Date Discl. Rec'd: MAY 13 2003

INVENTION DISCLOSURE FORM

ADVANCED CARDIOVASCULAR SYSTEMS, INC.

This is a form for disclosing ideas and inventions to the Guidant Legal Department for patent consideration. This form may be used before experimental work has been done. While some of the requested information may not be available at this time, include as much information as you can about the invention. Attach additional sheets if necessary, and sign and date each sheet. Additional information will be requested later.

Please complete each indicated area and return to Intellectual Property Paralegal, Guidant Vascular Intervention Group, 3200 Lakeside Drive, Santa Clara, CA 95052, and a copy to the R&D Director.

1. **DESCRIPTIVE TITLE OF THE INVENTION:** Poly (Ester Amide) (PEA)/Low Surface Energy Polymer Blends for Release Rate Control and Mechanical Property Enhancement

KEY WORDS: Stent, Drug delivery, PEA, Shear, Stent delivery

2. Submitter(s): *(please provide your full name, including middle name)*

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Empl. No. **028572**	Division Name: **DES Strategic Unit**	Manager Name: **Bob McGreevy**	

Inventor 2			
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Citizenship: **Bangladeshi**	Home phone no.: **510-797-8683**		
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Inventor 3			
Full Name: **Stephen Dirk Pacetti**	Signature: Stephen Pacetti		
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Citizenship: **USA**	Home phone no.: **408-370-1496**		
Work no.: **408-845-3452**	Work fax no.: **408-845-3689**		
Empl. No. **017953**	Division Name: **DES Strategic Unit**	Manager Name: **Murthy Simhambhatla**	

Inventor 4			
Full Name: **Eveleen Tang**	**Signature:**		
Home address: **#223, 1230 San Tomas Aquino Rd.**	City: **San Jose**	State: **CA**	Zip: **95117**
Citizenship: **Canada**	Home phone no.: **408 260 6888**		
Work no.: **408 845 1716**	Work fax no.: **408 845 3689**		
Empl. No. **027598**	Division Name: **DES**	Manager Name: **Gene Park**	

Inventors initials:
1 JRD 2 SH 3 S.F. 4 MT 5____ 6____ 7____ 8____ 9____

3. Invention Applicability/Project/Release/Sale Information
To which division or operation does this invention best apply? Stent
Field of Technology: Drug Delivery Stent
Related Invention Disclosure Docket Nos.: TBD
Project Name/Description: Drug Delivery Stent
Product Name: TBD
Estimated/actual manufacturing release date of invention or product incorporating or using the invention: TBD (date)
Estimated/actual date of offer for sale of product incorporating or using the invention: TBD (date)

4. DESCRIPTION AND USE

(a) Describe the invention in as much detail as possible, and include a description of a working prototype, if any. Write your description using reference numerals placed on a drawing. Point out and explain relationship with associated equipment. (b) How is the invention used? (c) How does it relate to present or potential commercial products of the company or others? (d) State the significance of the invention, and any problems it is intended to solve. Please supplement when possible by attaching sketches, engineering drawings, pages from lab books, photographs, and the like.

INTRODUCTION

Poly (Ester Amide) (PEA) currently is being investigated within Guidant as a bioabsorbable drug eluting stent coating. PEA has some very promising attributes, such as excellent biocompatibility in a 28-day porcine model and the ability to control the release of everolimus.

Generally, polymers with poor mechanical integrity are ruled out as potential DES coatings early on.

The fact that PEA already has demonstrated excellent biocompatibility *in vivo* and that it is the only bioabsorbable polymer in our portfolio able to control drug release makes it too valuable a material to rule out.

Inventors initials:
1 DD 2 SH 3 BR 4 [illegible] 5____ 6____ 7____ 8____ 9____

As an example, Fig. 1 shows a scanning electron micrograph of a PEA Benzyl Ester coated Vision stent depicting the typical type of mechanical failure observed upon deployment. In this example, the stent was crimped and icy hot processed onto a Vision catheter, e-beam sterilized, and then expanded to 16 atm in the simulated use apparatus.

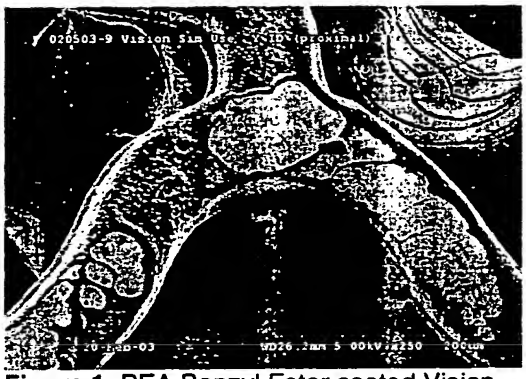


Figure 1. PEA Benzyl Ester coated Vision post-simulated use showing mechanical failure due to balloon shear.

Since the mechanical failures exhibited by PEA coated stents originate from the adhesive properties of the polymer, which cause the stent to stick to the catheter balloon, decreasing or eliminating the adhesive interaction between the PEA coating and the balloon should result in enhanced mechanical properties.

(a) **DISCLOSURE**

What is disclosed is a method for improving the mechanical and release rate properties of PEA by blending it with low surface energy, surface blooming polymers. The concept is to formulate a coating solution comprised of PEA, a spray solvent, and a low surface energy polymer. During the spray coating process, the low surface energy polymer will reside substantially at the air/liquid interface of the spray droplet. As the solvent evaporates, the coating surface becomes enriched in the low surface energy polymer, and the PEA component is pushed into the coating interior, thus preventing an interaction between PEA and the catheter balloon. The end result is a PEA-based coating with enhanced mechanical integrity.

Additionally, the low surface energy polymer can function to retard drug release from the PEA matrix by creating a hydrophobic barrier at the coating surface. This means that thinner coatings can be used to obtain the same release rate control. Incorporating a hydrophobic surface bloomer into the PEA matrix will have the added effect of altering the polymer degradation rate. As the hydrophobicity of the PEA blend is increased, the degradation rate will decrease, a desirable outcome since rapid degradation can promote inflammation. The hydrophobic surface bloomer does not need to be incorporated into all coating layers. For example, it could be added to only the to coat layer.

Inventors initials:
1 2 3 4 5 6 7 8 9

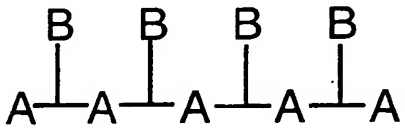
The hydrophobic surface blooming component could be a low surface energy polymer additive or it could be a block copolymer with a PEA miscible block and a hydrophobic surface modifier block. Since PEA is a bioabsorbable polymer, only other bioabsorbable polymers should be incorporated into the blend. Polymers that could function as hydrophobic surface modifiers include silwet surfactants, block copolymers of alkyl chains with polyglycol chains, Fluorad surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes encapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, and polyurethanes endcapped with polydimethylsiloxane. These surface blooming components can come in several configurations. One is a simple AB block copolymer where the A block is polymer miscible and the B block is the hydrophobic and surface blooming.

A—B

Another configuration is where the polymer is of BAB type where the surface blooming groups are at either end.

B—A—B

Still another arrangement is where the polymer miscible backbone "A" has surface blooming groups B grafted to it along its length.



To generalize, the polymer segment "A" is intended to be polymer miscible to keep the surface blooming additive in the coating. It can be a polyurethane, poly(ester-urea)urethane, polygycol such as poly(tetramethylene glycol) or poly(propylene glycol), polycaprolactone, EVAL, poly(butyl methacrylate), poly(methacrylate), or poly(acrylate). Group "B' can be selected from a linear or branched alkyl chain, poly(dimethylsiloxane), or a linear or branched perfluoro chain.

The objective is to create a PEA-based DES coating with enhanced mechanical and release rate properties.

(b) HOW IS THE INVENTION USED?
The focus of the invention lies in the area of DES coating formulation. Blending PEA with a hydrophobic surface blooming polymer will give a DES coating with acceptable mechanical integrity and release rate control. Once the hydrophobic surface modifier is chosen, the formulation will be coated using our current spray coating process.

Inventors initials:
1 QRD 2 SH 3 L.P. 4 [illegible] 5____ 6____ 7____ 8____ 9____

5. PROJECTED GENERIC SCOPE

Describe the invention in terms of the ***broadest*** generic scope which you expect will be operable (e.g. if a machine or article, describe alternate type and sizes of materials for construction, etc.; if a process, describe alternate manufacturing conditions, etc.).

A formulation where a low surface energy polymer is incorporated into the coating for the purpose of improving mechanical and release rate properties could be used on any drug eluting stent. Such coatings can be used on balloon expandable or self-expanding stents. This stent may be utilized in any part of the vasculature including neurological, carotid, coronary, renal, aortic, iliac, femoral, or other peripheral vasculature. There is no inherent limitation on the length, diameter, strut pattern, or strut thickness.

6.

Has a literature search been made? Yes_____ No __X____ Don't know_____

If "Yes", list and if possible, attach copies of all literature, publications, patents and applications of which are relating to the invention. See section in Guidelines for Completing Invention Disclosure Form concerning obligation of disclosure.

Is this invention an improvement of an existing company product? Yes__X___ No _____ Don't know_____
If "Yes" identify the product: _Endoluminal Stents____

List the closest known prior art/technology: _Stents____

Inventors initials:
1 GRD 2 SH 3 J.P. 4 [illegible] 5____ 6____ 7____ 8____ 9____

7. Publication of the Invention

What is the current stage of development of the invention? Concept

Has a description been published or is it scheduled to be published? Yes_____ No __X___ Don't know_____
Has a description been disclosed or is it scheduled to be disclosed outside of Guidant?
Yes_____No __X____Don't know_____

If "Yes", when and to whom? _____

Was a Non-Disclosure Agreement used? Yes_____No _____Don't know_____

If "Yes", please attach a copy of the agreement to the disclosure.

8. Joint Development of Development Contract

Was this invention made under a government agency contract? Yes_____No __X____Don't know_____

If "Yes":
• List all non-Guidant inventors: _____

• List all government contract numbers: _____

9. Witness Signature (not a submitter)

Read and understood the completed Invention Disclosure Form

Steve Dugan
Printed Name

Signature 5/13/03
Date

Inventors initials:
1 JRD 2 SH 3 S.P. 4 [illegible] 5____ 6____ 7____ 8____ 9____